

**REMARKS**

Claims 8-17, 38 and 39 have been cancelled. Claims 1-3, 34 and 35 have been amended. Claims 1-3, 34 and 35 have been amended to recite “the pro-inflammatory action of,” and deletion of the phrase “neutralizing epitope”. Support can be found in the specification, for example, at page 2, lines 1-30, and in the priority document 07/670,827, for example, at page 3, line 13 and page 10, lines 22-25. Claims 1-3, 34 and 35 incorporate a proviso, and support for the proviso found in the specification, for example, at page 57, lines 25-26, and in priority document 08/013,413, for example, at page 35, line 18. Claims 1, 2, 3, 34, and 35 have been amended to recite “monoclonal.” Support for these amendments is found in the specification at page 17, lines 2-3 and page 19, lines 7-24, and priority document 07/670,827 at page 6, line 8. No new matter is added. Therefore, entry of the amendments into the application is respectfully requested.

**Priority**

U.S. Application No.: 08/013,413, filed February 2, 1993, discloses the treatment of neurodegenerative diseases, including the elected species ALS.

Applicants disagree with the statement that “neither the priority applications nor the instant application provides a sufficient description of a representative number of species to represent the entire genus of “neurodegenerative diseases” as well as the specific recitation of neurodegenerative diseases (e.g. ALS), as currently claimed.”

Furthermore, USSN 08/013,413 certainly claims a representative number of species to represent the entire genus of “neurodegenerative diseases”.

As recited on page 35, line 16 to page 36, line 2, neurodegenerative species disclosed include: neurodegenerative diseases.

AIDS dementia complex, demyelinating diseases, such as multiple sclerosis and acute transverse myelitis; extrapyramidal and cerebellar disorders' such as lesions of the corticospinal system; disorders of the basal ganglia or cerebellar disorders; hyperkinetic movement disorders such as Huntington's Chorea and senile chorea; drug-induced movement disorders, such as those induced by drugs which block CNS dopamine receptors; hypokinetic movement disorders, such as Parkinson's disease; Progressive supranucleo Palsy; structural lesions of the cerebellum;

spinocerebellar degenerations, such as spinal ataxia, Friedreich's ataxia, cerebellar cortical degenerations, multiple systems degenerations (Mencel, Dejerine-Thomas, Shi-Drager, and Machado-Joseph); systemic disorders (Refsum's disease, abetalipoproteinemia, ataxia, telangiectasia, and mitochondrial multi-system disorder); demyelinating core disorders, such as multiple sclerosis, acute transverse myelitis; and disorders of the motor unit' such as neurogenic muscular atrophies (anterior horn cell degeneration, such as amyotrophic lateral sclerosis, infantile spinal muscular atrophy and juvenile spinal muscular atrophy); Alzheimer's disease; Down's Syndrome in middle age; Diffuse Lewy body disease; Senile Dementia of Lewy body type; Wernicke-Korsakoff syndrome; chronic alcoholism; Creutzfeldt-Jakob disease; Subacute sclerosing panencephalitis Hallerorden-Spatz disease; and Dementia pugilistica.

The MPEP recites no definitive number of species to constitute a genus. Applicants submit that the list above is representative of the genus “neurodegenerative disease”.

Applicants further submit that literal support for “neurodegenerative diseases” and “ALS” is found in USSN 08/013,413, filed 2/2/93, as indicated above.

#### Claim Objections

Claims 15 and 16 are objected to as failing to provide proper antecedent basis for the claimed subject matter under 37 C.R.R. §1.75(d)(1) and MPEP §608.01(1).

Applicants have cancelled claims 15 and 16 rendering the objection moot.

#### Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-7, 15-16, 18-20 and 22-39 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have amended the claims to recite methods of inhibiting “the pro-inflammatory action of TNF $\alpha$  in a human patient” having neurodegenerative disease. In certain embodiments, the patient has ALS. Applicant submit that in view of this amendment and the arguments presented previously, the claims satisfy the enablement requirement. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-7, 15-16, 18-20 and 22-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le et al.* (WO 92/16553) in view of *Beck et al.* (*Acta Neurol. Scand.* 78:318-323, 1988) *Chofflon et al.* (*Eur. Cytokine Netw.* 3:523-531, 1992) and *Selmaj et al.* (*Ann Neurol.* 30: 694-700, 1991). Applicants respectfully disagree.

Applicants have amended the claims to recite methods of inhibiting the pro-inflammatory action of TNF $\alpha$  in a human patient. Further the claims have been amended to include the proviso that the neurodegenerative disease does not include multiple sclerosis. In view of these amendments, the art cited by the Examiner whether considered alone or in combination does not render Applicants' invention obvious. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under the Judicially Created Doctrine of Obviousness-type Double Patenting

Claims 1-7, 15-16, 18-20 and 22-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,991,791. Applicants will address this matter in regard to the pending claims upon indication of allowable claims.

Provisional Rejection Under the Judicially Created Doctrine of Obviousness-type Double Patenting

Claims 1-7, 15-16, 18-20 and 22-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 4, 5, 7-10, 12, 14, 21, 23-24, 30, 35, 37 and 52-89 of copending U.S. Patent Application No. 10/227,488 (0975.1005-025).

Applicants will address this matter in regard to the pending claims upon indication of allowable claims.

**Information Disclosure Statement**

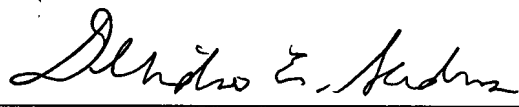
A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

**CONCLUSION**

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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